

REMARKS

Claim Rejections – 35 USC § 103

Claims 44-67 have been rejected by the Examiner under 35 USC 103(a).

Claims 44-67 have been canceled without prejudice. New claims 68-83 have been added. The new claims 68-79 have been introduced to better represent the subject matter of the previously presented claims 44-67. No new matter has been introduced. See, e.g., Figures 12A, 12B and 12D, ¶¶s 54, 69, 75, 76, 78, 79, 93, 98, 99, 100, and 102. Reconsideration and allowance are respectfully requested.

The prior art of record to Lange et al. (US 6,751,499) ("Lange") in view of Skrabal (US 5,097,834), even in combination, do not teach several limitations of the new independent claims 68 and 74.

Lange teaches a medical diagnostic system for measuring and reporting a subject's pain. The system operates outside of the patient's body. While Lange teaches measurement of blood pressure, pulse, temperature, respiration, and the patient's pain level, all of these measurements are performed external to the subject.

As agreed to by the Examiner in the previous office action, Lange is not configured to be implanted in the patient's body and to drain fluid from the vicinity of tissue, as required by the present claims. The system of the new claims 68 and 74 specifically require a surgical drain that is configured to be implanted in a patient's body and configured to house at least one transmitter and one sensor.

Aside from not teaching an implantable device for draining fluid from inside of a patient's body, Lange also fails to teach a surgical drain that is configured to house at least one transmitting and one sensing elements that are configured to be implanted with surgical drain in the patient's body.

Unlike the present claims, Lange's system is not configured to be implanted in the body, rest against the surface of tissue within the patient's body, transmit energy to the tissue surface, and to sense the energy emitted from the tissue surface. Lange fails to teach detection of spectral energy from a tissue surface within the body. The cited passages do not disclose detection of spectral energy and a processor to determine the color (claim 68) or numerical color value (claim 74) representation of the detected spectral energy. Lange only discloses a label-like color coded strip installed on the patient's forehead to display a color as previously assigned to an intensity level. Lange does not teach a processor that determines the color (claim 68) or numerical color value (claim 74) representation of a tissue based on the detected spectral energy, an important feature in determining the condition of the patient's tissue.

Therefore, Lange fails to teach required limitations of independent claims 68 and 74 as discussed above.

Skrabal discloses a device that determines a degree of interaction between an exogenous perfusion fluid and tissue, requiring injection of this exogenous perfusion fluid into the tissue. Skrabal's injection device is not configured to *rest against* the surface of tissue and drain fluid from the vicinity of tissue as required by present claims 68 and 74.

Additionally, Skrabal does not teach the presently claimed surgical drain that is configured to house at least one sensing element and at least one transmitting element, and to rest against a tissue surface. Specifically, Skrabal's sensors are located outside of the patient's body. Furthermore, Skrabal teaches away from having the sensing elements on the device within the body (See Column 1, Lines 7-21).

Independent claims 68 and 74 also include the limitation of "wherein the surgical drain is not configured to penetrate the tissue area". Skrabal's device must directly penetrate the tissue in order to release the perfusion fluid into the tissue. Skrabal does not teach a device that rests against the tissue, as required by the present claims. Moreover, Skrabal's device will not work without penetration into the tissue.

On page 4 of the office action, the Examiner asserted that Skrabal discloses a pump 16 that delivers energy to the tissue. Applicant respectfully disagrees. Pumping fluid does not deliver energy to tissue.

The office action also was silent with regards to the processor that is configured to determine and display a numerical color value based on the detected spectral energy, as previously required by claim 56 and now required by the independent claim 75. Skrabal does not teach this limitation of the claim.

Even in combination, Lange et al. in view of Skrabal fail to teach several limitations of independent claims 68 and 74. These include a surgical drain system configured to rest against the surface of a tissue in a patient's body, a

surgical drain configured to house a transmitting element, a surgical drain configured to drain fluid from the vicinity of tissue, a surgical drain having a transmitting element integrated with an outer surface of the drain and configured to deliver energy to a tissue area, a surgical drain with a sensing element integrated with an outer surface and configured to detect spectral energy emitted from the first tissue area that is derived from delivered energy, and a processor configured to determine a color or color value representative of detected spectral energy.

There was also no motivation to combine the selected teaching of Lange and Skrabal. To the contrary, Lange's device relied on electrodes attached to the patient body to measure electrical signals that were translated to quantify the sensation of pain. Skrabal's device relied on electrodes that measured the concentration of substances in a fluid withdrawn from the body after the fluid equilibrated with the tissue. These were two different kinds of sensors (sensing off the live patient versus sensing off a fluid) and different sensing approaches (real-time versus off-line) that could not readily even have been combined. The Lange's sensors measured real-time electrical signals directly from the patient's body while Skrabal's measured stationary concentration signals from the fluid that has been already withdrawn out of the tissue. Using Skrabal's sensors would not have even allowed Lange's device to have acquired the real-time electrical signals required for pain detection. It was well known that pain was transmitted as real-time electrical signals through a network of nerves to the brain.

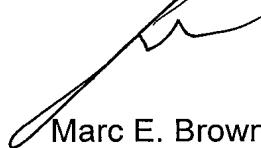
Claims 69-73 and 75-79 variously depend from claims 68 and 74 and are therefore thus also not obvious in view of Lange et al. and Skrabal.

CONCLUSION

The Applicant respectfully submits that the above remarks place this application in a condition for allowance, which the Applicant respectfully solicits.

A petition for a three-month extension of time under 37 C.F.C. 1.136 is being filed contemporaneously herewith. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 501946 and please credit any excess fees to such deposit account and reference attorney docket no. 64693-92.

Respectfully submitted,
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